

I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV534444713US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

Dated: May 15, 2007

Signature: *Rosemarie Puljic-Salmeron*

(Rosemarie Puljic-Salmeron)

Patent

Docket No. 608352000100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of:
Tania KASTELIC et al.

Serial No.: 10/814,634

Filing Date: April 1, 2004

For: ASSAY FOR IDENTIFYING
COMPOUNDS WHICH AFFECT
STABILITY OF MRNA

Examiner: C. Qian

Group Art Unit: 1636

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. U.S. Patent/Patent Applications (documents numbered 1, 2 and 8) are not submitted herewith. Copies of foreign documents and non-patent literature (documents numbered 12, 14, 15, 19, 26, 30-35, 38, 46, 47, 49, 55 and 59) are submitted herewith. However, copies of the remaining documents cited in the attached Form PTO/SB/08a/b were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/869,159, filed August 15, 2001, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

05/18/2007 MBLANCO 00000002 031952 10014634
100.00 DA

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☒ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 608352000100.

Dated: May 15, 2007

Respectfully submitted,

By Jill A. Jacobson
Jill A. Jacobson
Registration No.: 40,030
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5876



ALTERNATIVE TO PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/814,634
				Filing Date	April 1, 2004
				First Named Inventor	Tania KASTELIC
				Art Unit	1636
				Examiner Name	C. Qian
Sheet	1	of	4	Attorney Docket Number	608352000100

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	US-2004/0214223-A1	10-28-2004	Cao et al.	
	2.	US-2005/0048549-A1	03-03-2005	Cao et al.	
	3.	US-5,444,149-A	08-22-1995	Keene et al.	
	4.	US-5,587,300-A	12-24-1996	Malter	
	5.	US-5,698,427-A	12-16-1997	Keene et al.	
	6.	US-5,731,343-A	03-24-1998	Feng et al.	
	7.	US-6,635,671-B1	10-21-2003	Kastelic et al.	
	8.	US-7,078,171-B2	07-18-2006	Giordano et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	9.	GB-9828707.1	02-17-1999	Novation Pharmaceuticals, Inc.		
	10.	GB-9828710.5	02-17-1999	Novation Pharmaceuticals, Inc.		
	11.	WO-93/20212-A1	10-14-1993	The Government of the United States of America as represented by The Secretary, Department of Health and Human Services		
	12.	WO-95/33831-A1	12-14-1995	Creative Biomolecules, Inc.		
	13.	WO-98/39484-A1	09-11-1998	Scriptgen Pharmaceuticals, Inc.		
	14.	WO-00/39314-A1	07-06-2000	Novation Pharmaceuticals, Inc.		
	15.	WO-2004/065561-A2	08-05-2004	PTC Therapeutics, Inc.		

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	16.	Akashi, M. et al. (1994). "Number and Location of AUUUA Motifs: Role in Regulating Transiently Expressed RNAs," <i>Blood</i> 83:3182-3187.		
	17.	Auwerx, J. (1991). "The Human Leukemia Cell Line, THP-1: A Multifaceted Model for the Study of Monocyte-Macrophage Differentiation," <i>Experienta</i> 47:22-31.		
	18.	Banholzer, R. et al. (June 1997). "Rapamycin Destabilizes Interleukin-3 mRNA in Autocrine Tumor Cells by a Mechanism Requiring an Intact 3' Untranslated Region," <i>Molecular and Cellular Biology</i> 17(6):3254-3260.		
	19.	Bernstein, P.L. et al. (April 1992). "Control of c-myc mRNA Half-Life in vitro by a Protein Capable of Binding to a Coding Region Stability Determinant." <i>Genes Dev.</i> 6(4):642-654.		

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

pa- 1121349

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/814,634
				Filing Date	April 1, 2004
				First Named Inventor	Tania KASTELIC
				Art Unit	1636
				Examiner Name	C. Qian
Sheet	2	of	4	Attorney Docket Number	608352000100

20.	Beutler, B. et al. (1988). "Assay of a Ribonuclease That Preferentially Hydrolyses mRNAs Containing Cytokine-Derived UA-Rich Instability Sequences," <i>Biochem. Biophys. Res. Comm.</i> 152:973-980.
21.	Chen, C.-Y.A. et al. (1994). "Interplay of Two Functionally and Structurally Distinct Domains of the c-fos AU-Rich Element Specifies Its mRNA-Destabilizing Function," <i>Mol. Cell. Biol.</i> 14:416-426.
22.	Chen, C.-Y.A. et al. (1994). "Selective Degradation of Early-Response-Gene mRNAs: Functional Analyses of Sequence Features of the AU-Rich Elements," <i>Mol. Cell. Biol.</i> 14:8471-8482.
23.	Chen, C.-Y.A. et al. (1995). "AU-Rich Elements: Characterization and Importance in mRNA Degradation," <i>TIBS</i> 20:465-470.
24.	Chen, C.-Y.A. et al. (1995). "mRNA Decay Mediated by Two Distinct AU-Rich Elements from c-fos and Granulocyte-Macrophage Colony-Stimulating Factor Transcripts: Different Deadenylation Kinetics and Uncoupling from Translation," <i>Mol. Cell. Biol.</i> 15:5777-5788.
25.	Claffey, K.P. et al. (February 1998). "Identification of a Human VPF/VEGF 3' Untranslated Region Mediating Hypoxia-Induced mRNA Stability," <i>Mol. Biol. Cell</i> 9:469-481.
26.	Cleveland, D.W. et al. (November 1989). "Multiple Determinants of Eukaryotic mRNA Stability," <i>New. Biol.</i> 1(2):121-126.
27.	Crawford, E.K. et al. (August 1997). "The Role of 3' Poly(A) Tail Metabolism in Tumor Necrosis Factor- α Regulation," <i>J. Biol. Chem.</i> 272:21120-21127.
28.	Danner, S. et al. (February 1998). "Agonist Regulation of Human β_2 -Adrenergic Receptor mRNA Stability Occurs via a Specific AU-Rich Element," <i>J. Biol. Chem.</i> 273:3223-3229.
29.	Fan, X.C. (June 1998). "Overexpression of HuR, a Nuclear-Cytoplasmic Shuttling Protein, Increases the <i>in vivo</i> stability of ARE-Containing mRNAs," <i>EMBO J.</i> 17:3448-3460.
30.	GenBank Accession No. AF022375, created October 7, 1998, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=3719220 >, last visited on February 7, 2007, two pages.
31.	GenBank Accession No. D10493, created May 29, 2002, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=219932 >, last visited on February 7, 2007, seven pages.
32.	GenBank Accession No. M13994, created October 31, 1994, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=179366 >, last visited on December 29, 2006, three pages.
33.	GenBank Accession No. U40398, created March 13, 1997, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=1117909 >, last visited on December 29, 2006, three pages.
34.	GenBank Accession No. X04500, created November 14, 2006, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=33788 >, last visited on December 29, 2006, six pages.
35.	GenBank Accession No. Y00264, created September 12, 1993, located at < http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=28525 >, last visited on December 29, 2006, three pages.
36.	Gil, P. et al. (1996). "Multiple Regions of the <i>Arabidopsis</i> SAUR-AC1 Gene Control Transcript Abundance: the 3' Untranslated Region Functions as a mRNA Instability Determinant," <i>EMBO J.</i> 15:1678-1686.
37.	Heaton, J.H. et al. (June 1998). "Cyclic Nucleotide Regulation of Type-1 Plasminogen Activator-Inhibitor mRNA Stability in Rat Hepatoma Cells," <i>J. Biol. Chem.</i> 273:14261-14268.
38.	International Search Report mailed June 6, 2000, for PCT Application No. PCT/CA99/01235 filed December 23, 1999, three pages.
39.	Kastelic, T. et al. (October 1996). "Induction of Rapid IL-1 β mRNA Degradation in Thp-1 Cells Mediated Through the AU-rich Region in the 3' UTR by a Radcicol Analogue," <i>Cytokine</i> 8(10):751-761.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/814,634
				Filing Date	April 1, 2004
				First Named Inventor	Tania KASTELIC
				Art Unit	1636
				Examiner Name	C. Qian
Sheet	3	of	4	Attorney Docket Number	608352000100

40.	Klausner, R.D. et al. (1993). "Regulating the Fate of mRNA: The Control of Cellular Iron Metabolism," <i>Cell</i> 72:19-28.
41.	Kobayashi, M. et al. (July 1998). "Characterization of the 3' Untranslated Region of Mouse DNA Topoisomerase II α mRNA," <i>Gene</i> 215:329-337.
42.	Lagnado, C.A. et al. (1994). "AUUUA Is Not Sufficient to Promote Poly(A) Shortening and Degradation of an mRNA: The Functional Sequence Within AU-Rich Elements May Be UUAUUUA(U/A)(U/A)," <i>Mol. Cell. Biol.</i> 14:7984-7995.
43.	Levy, A.P. et al. (1996). "Post-Transcriptional Regulation of Vascular Endothelial Growth Factor by Hypoxia," <i>J. Biol. Chem.</i> 271:2746-2753.
44.	Levy, J.R. et al. (1995). "Sequence and Functional Characterization of the Terminal Exon of the Human Insulin Receptor Gene," <i>Biochim. Biophys. Acta</i> 1263:253-257.
45.	Lewis, T. et al. (May 1998). "Mapping of a Minimal AU-Rich Sequence Required for Lipopolysaccharide-Induced Binding of a 55-kDa Protein on Tumor Necrosis Factor- α mRNA," <i>J. Biol. Chem.</i> 273:13781-13786.
46.	Mitchell, P. et al. (April 2000). "mRNA Stability in Eukaryotes," <i>Curr. Opin. Genet. Dev.</i> 10:193-198.
47.	Mitchell, P. et al. (June 2001). "mRNA Turnover," <i>Curr. Opin. Cell. Biol.</i> 13(3):320-325.
48.	Nanbu, R. et al. (1994). "Multiple Instability-Regulating Sites in the 3' Untranslated Region of the Urokinase-Type Plasminogen Activator mRNA," <i>Mol. Cell. Biol.</i> 14:4920.
49.	Ross, J. (September 1995). "mRNA Stability in Mammalian Cells," <i>Microbiol. Rev.</i> 59(3):423-450.
50.	Sachs, A.B. (1993). "Messenger RNA Degradation in Eukaryotes," <i>Cell</i> 74:413-421.
51.	Sambrook, J. et al. (1989). "Calcium Phosphate-Mediated Transfection of Adherent Cells in Suspension" <i>In</i> Chapter 16 <i>In Molecular Cloning A Laboratory Manual</i> , Cold Spring Harbor Laboratory Press: Cold Spring Harbor, NY, pp. 16.37.
52.	Sambrook, J. et al. (1989). "Standard Protocol for Calcium Phosphate-Mediated Transfection of Adherent Cells" <i>In</i> Chapter 16 <i>In Molecular Cloning A Laboratory Manual</i> , Cold Spring Harbor Laboratory Press: Cold Spring Harbor, NY, pp. 16.33-16.36.
53.	Shaw, G. et al. (1986). "A Conserved AU Sequence from the 3' Untranslated Region of GM-CSF mRNA Mediates Selective mRNA Degradation," <i>Cell</i> 46:659-667.
54.	Shyu, A.-B. et al. (1991). "Two Distinct Destabilizing Elements in the c-fos Message Trigger Deadenylation as a First Step in Rapid mRNA Decay," <i>Genes & Development</i> 15:221-231.
55.	Staton, J.M. et al. (August 2000). "Hormonal Regulation of mRNA Stability and RNA-Protein Interactions in the Pituitary," <i>J. Mol. Endocrinology</i> 25(1):17-34.
56.	Stoecklin, G. et al. (1994). "Functional Hierarchy of AUUUA Motifs in Mediating Rapid Interleukin-3 mRNA Decay," <i>J. Biol. Chem.</i> 269:28591-28597.
57.	Stolle, C.A. et al. (1988). "Cellular Factor Affecting the Stability of β -Globin mRNA," <i>Gene</i> 62:65-74.
58.	Sullivan, M.L. et al. (1996). "Mutational Analysis of the DST Element in Tobacco Cells and Transgenic Plants: Identification of Residues Critical for mRNA Instability," <i>RNA</i> 2:308-315.
59.	Wilusz, C.J. et al. (April 11, 2001). "The Cap-To-Tail Guide to mRNA Turnover," <i>Nat. Rev. Mol. Cell. Biol.</i> 2(4):237-246.
60.	Winstall, E. et al. (1995). "Rapid mRNA Degradation Mediated by the c-fos 3' AU-Rich Element and That Mediated by the Granulocyte-Macrophage Colony-Stimulating Factor 3' AU-Rich Element Occur Through Similar Polysome-Associated Mechanisms," <i>Mol. Cell. Biol.</i> 15:3796-3804.
61.	Xu, N. et al. (August 1997). "Modulation of the Fate of Cytoplasmic mRNA by AU-Rich Elements: Key Sequence Features Controlling mRNA Deadenylation and Decay," <i>Mol. Cell. Biol.</i> 18:4611-4621.
62.	Zhang, G. et al. (October 23, 1996). "An Enhanced Green Fluorescent Protein Allows Sensitive Detection of Gene Transfer in Mammalian Cells," <i>Biochemical and Biophysical Research Communications</i> 227(3):707-711.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/814,634
				Filing Date	April 1, 2004
				First Named Inventor	Tania KASTELIC
				Art Unit	1636
				Examiner Name	C. Qian
Sheet	4	of	4	Attorney Docket Number	608352000100

	63.	Zhang, S. et al. (1995). "Identification and Characterization of a Sequence Motif Involved in Nonsense-Mediated mRNA Decay," <i>Mol. Cell. Biol.</i> 15:2231-2244.	
	64.	Zubiaga, A.M. et al. (April 1995). "The Nonamer UUAUUUAUU Is the Key AU-Rich Sequence Motif That Mediates mRNA Degradation," <i>Molecular and Cellular Biology</i> 15(4):2219-2230.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--